

# **Exhibit “J”**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

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**IN RE: ETHICON, INC.,  
PELVIC REPAIR SYSTEM**

**PRODUCTS LIABILITY LITIGATION**  
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**Civil Action No. MDL 2327  
Action Pending in the: Southern  
District of West Virginia  
Charleston Division**

**PLAINTIFFS' NOTICE OF ISSUANCE OF SUBPOENA TO ADVANCED MEDICAL  
TECHNOLOGY ASSOCIATION ("ADVAMED")**

PLEASE TAKE NOTICE that testimony will be taken by video deposition upon oral examination, pursuant to Federal Rule of Civil Procedure 45, pursuant to the Subpoena attached hereto, and that Plaintiffs intend to serve said Subpoena on Advanced Medical Technology Association ("AdvaMed") on December 7, 2012, or as soon thereafter as service may be effectuated.

Date: 12/07/2012

Respectfully Submitted,

/s/Bryan F. Aylstock  
Bryan Frederick Aylstock  
AYLSTOCK WITKIN KREIS & OVERHOLTZ, PLLC  
Florida Bar No.: 78263  
17 E. Main St., Ste. 200  
Pensacola, Florida 32502  
Telephone: 850.202.1010  
Facsimile: 850.916.7449  
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I declare under penalty of perjury that, on December 7, 2012, on behalf of the Plaintiffs' Steering Committee, In Re Ethicon, Inc., Pelvic Repair System Products Liability Litigation, MDL No. 2327, I served the foregoing *Notice of Subpoena* by Electronic Mail upon:

Christy D. Jones  
Christy.jones@butlersnow.com  
Butler, Snow, O'Mara, Stevens & Cannada, PLLC  
1020 Highland Colony Parkway  
Suite 1400  
Ridgeland, MS 39157  
601/948-5711  
601/985-4500 (fax)

/s/Bryan F. Aylstock  
Bryan Frederick Aylstock  
AYLSTOCK WITKIN KREIS & OVERHOLTZ, PLLC  
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Pensacola, Florida 32502  
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baylstock@awkolaw.com

## UNITED STATES DISTRICT COURT

for the

District of Columbia

*Plaintiff*

v.

In Re: Ethicon, Inc., Pelvic Repair System Products  
Liability Litigation*Defendant*

Civil Action No. MDL No. 2327

(If the action is pending in another district, state where:

Southern District of West Virginia )

## SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Advanced Medical Technology Association, 701 Pennsylvania Avenue, N.W., Suite 800, Washington, DC 20004

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

All records described in Exhibit "A" (attached)

Place: Ashcraft & Gerel LLP  
2000 L Street, N.W.  
Washington, DC 20036

Date and Time:

12/27/2012 10:00 am

The deposition will be recorded by this method: Video Depo Upon Oral Examination

☒ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

All records described in Exhibit "A" (attached)

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 12/7/2012

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* PlaintiffsBryan F. Aylstock

17 E. Main Street, Suite 200, Pensacola, FL 32502

baylstock@awkolaw.com

850-202-1010

, who issues or requests this subpoena, are:

Civil Action No. MDL No. 2327

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

This subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named individual as follows: \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:

**Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)****(c) Protecting a Person Subject to a Subpoena.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

**(A) Appearance Not Required.** A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

**(B) Objections.** A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

**(i)** At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

**(ii)** These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

**(A) When Required.** On timely motion, the issuing court must quash or modify a subpoena that:

**(i)** fails to allow a reasonable time to comply;

**(ii)** requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

**(iii)** requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

**(iv)** subjects a person to undue burden.

**(B) When Permitted.** To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

**(i)** disclosing a trade secret or other confidential research, development, or commercial information;

**(ii)** disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

**(iii)** a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

**(C) Specifying Conditions as an Alternative.** In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

**(i)** shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

**(ii)** ensures that the subpoenaed person will be reasonably compensated.

**(d) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

**(A) Documents.** A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

**(B) Form for Producing Electronically Stored Information Not Specified.** If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

**(C) Electronically Stored Information Produced in Only One Form.** The person responding need not produce the same electronically stored information in more than one form.

**(D) Inaccessible Electronically Stored Information.** The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

**(A) Information Withheld.** A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

**(i)** expressly make the claim; and

**(ii)** describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

**(B) Information Produced.** If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(e) Contempt.** The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

**EXHIBIT A**

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1. Pursuant to Federal Rule of Civil Procedure 45, testimony will be taken by video deposition upon oral examination before a person authorized by the laws of the District of Columbia to administer oaths on **DECEMBER 27, 2012 at 10:00 a.m.** at the office of Ashcraft & Gerel LLP located at 2000 L Street, N.W., Washington, D.C. 20036, as set forth in the attached Subpoena. Said deponent appearing on behalf of AdvaMed shall be the person/ representative with the most knowledge concerning the membership, activities and/or participation of the transvaginal surgical mesh manufacturers within AdvaMed's organization, including but not limited to the following:

- a. Acell;
- b. American Medical Systems, Inc. ("AMS") and/or American Medical Systems Holdings, Inc. ("AMS Holdings");
- c. Bio-vascular, Inc.;
- d. Boston Scientific Corporation;
- e. Brennen Medical, Inc.;
- f. C.R. Bard, Inc. ("Bard");
- g. Caldera Medical, Inc.;
- h. Coloplast A/S;
- i. Cook Biotech, Inc.;
- j. Cousin Biotech S.A.R.L.;
- k. Cryolife, Inc.;
- l. Endo Pharmaceuticals, Inc., Endo Health Solutions, Inc. (f/k/a Endo Pharmaceutical Holdings, Inc.);

- m. Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare, and/or Johnson & Johnson, Inc. ("Ethicon");
- n. GFE Medixinteknik GmbH;
- o. Herniamesh SRL;
- p. Kensey Nash Corporation;
- q. Macropore Biosurgery Inc.;
- r. Mpathy Medical Devices, Ltd.;
- s. Neomedic International;
- t. Organogenesis, Inc.;
- u. Osteobiologics, Inc.;
- v. Pegasus Biologics, Inc.;
- w. Promethean Surgical Devices, Inc.;
- x. Proxy Biomedical, Ltd.;
- y. RTI Biologics, Inc.;
- z. Shelhigh, Inc.;
- aa. Sofradim Production SAS ("Sofradim");
- bb. Synovis Surgical Innovations;
- cc. TEI Biosciences, Inc.;
- dd. Tepha, Inc.;
- ee. Covidien (Tissue Science Laboratories, PLC) ("TSL");
- ff. W.L. Gore & Associates, Inc.;
- gg. Xylos Corporation;
- hh. Gyne Ideas, Ltd.; and
- ii. Prosurg, Inc.



2. That said deponent shall be the person/ representative with the most knowledge concerning AdvaMed and its members' activities and communications relating to the safety and efficacy of transvaginal surgical mesh products, and any communications and submissions to the United States Food and Drug Administration ("FDA") relating to transvaginal surgical mesh products, including but not limited to the following:

- a. Preparation, attendance, or presentation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee entitled "Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse";
- b. Preparation, attendance, and/or presentation by AdvaMed during the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee;
- c. Preparation, attendance, and/or presentation to any domestic and/or foreign governmental body, representative, or agency;
- d. Preparation, attendance, and/or presentation to any legislator, healthcare provider, medical societies, and/or medical technology conferences;
- e. The industry working group known as the "Transvaginal Mesh Industry Working Group," including scientific literature and reports reviewed;
- f. Involvement of the media relations organization known as "newsPRO;" and
- g. Any communications and submissions made in anticipation to or in response to, and otherwise relating to, the FDA's "Section 522 Order" issued in January 2012.

3. That said deponent shall be the person/representative that possesses the following documents, tangible things and electronically stored information within the possession, custody, and control of the witness pursuant to Fed. R. Civ. P. 26 and Rule 45, as set out below.

**A. Definitions**

The following definitions are applicable to the request for documents to be produced by Advanced Medical Technology Association ("AdvaMed") as described herein:

1. The terms “documents” or “electronically-stored information” is ascribed the meaning set forth in Federal Rule of Civil Procedure 34.1(a)(1)(A).
2. The term “or” means and/or, and the term “and” means and/or.
3. The term “you” or “your” means the answering party, Advanced Medical Technology Association (“AdvaMed”).
4. The term “transvaginal surgical mesh” means all transvaginal surgical mesh products used for the treatment of pelvic organ prolapse (“POP”) or stress urinary incontinence (“SUI”).

**B. Categories of Documents to be Produced**

1. All documents concerning the risks, safety, or efficacy of transvaginal surgical mesh products from 2005 to present, including but not limited to the AdvaMed members and/or manufacturers identified *supra* at 1-2.
2. All documents concerning the preparation, presentation or attendance on behalf of AdvaMed or its transvaginal surgical mesh product manufacturer members during the Obstetrics and Gynecology Devices Panel of the United States Food and Drug Administration (“FDA”)’s Medical Devices Advisory Committee held on September 8 and 9, 2011, including but not limited to:
  - a. Preparation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel entitled “Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse”;
  - b. Scientific literature discussing the risks, safety and efficacy of transvaginal surgical mesh products;
  - c. Premarket clinical and preclinical studies, and postmarket studies evaluating the safety and effectiveness of transvaginal surgical mesh for the treatment of pelvic organ prolapse or stress urinary incontinence;

- d. The declassification of the transvaginal surgical mesh products to Class III (Premarket Approval);
  - e. Discussion, analysis of, or reference to FDA's 510(k) decision or submission process, including science reports; and
  - f. Premarket and postmarket review protocols, policies, or procedures.
3. All documents concerning the industry working group formed by AdvaMed from 2005 to present, known as the "Transvaginal Mesh Industry Working Group," including but not limited to the following concerning transvaginal surgical mesh products:
- a. Preparation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel entitled "Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse";
  - b. Scientific literature discussing the risks, safety and efficacy of transvaginal surgical mesh products;
  - c. Premarket clinical and preclinical studies, and postmarket studies evaluating the safety and effectiveness of transvaginal surgical mesh for the treatment of pelvic organ prolapse or stress urinary incontinence;
  - d. The declassification of the transvaginal surgical mesh products to Class III (Premarket Approval);
  - e. Discussion, analysis of, or reference to FDA's 510(k) decision or submission process, including science reports;
  - f. Premarket and postmarket review protocols, policies, or procedures;
  - g. Meeting minutes, notes or memoranda from organizational group meetings; and
  - h. Any communications and submissions made in anticipation to or in response to, or otherwise relating to the FDA's "Section 522 Order" issued in January 2012.
4. All documents by AdvaMed or its member companies' relating to communications and submissions with or to legislators, regulators, domestic and foreign governmental bodies, health care providers, medical societies and patient organizations,

concerning the risks, safety, efficacy, or the FDA 510(k) decision or submission process, of transvaginal surgical mesh products from 2005 to present.

5. All documents or communications concerning the risks, safety, and efficacy of transvaginal surgical mesh products presented by AdvaMed at any medical technology conferences from 2005 to present.

6. All documents or communications by AdvaMed or its transvaginal surgical mesh product manufacturer members with the media relations organization “newsPROs,” concerning the risks, safety, efficacy, or the FDA 510(k) decision or submission process of the transvaginal surgical mesh products from 2005 to present.

7. All documents relating to the FDA’s “Section 522 Order” issued in January 2012.

Respectfully submitted,

Jeff Grand, Esq.  
BERNSTEIN LIEBHARD LLP

Bryan F. Aylstock, Esq.  
AYLSTOCK WITKIN KREIS &  
OVERHOLTZ, PLLC

Attorney for Plaintiffs’ Co-Lead Counsel for  
In Re: Ethicon, Inc., Pelvic Repair System  
Products Liability Litigation.  
MDL No. 2327

Dated: December 7, 2012